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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,708	12/30/2005	Margaretha Bakker	ABB10010P2080US	4819

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EXAMINER	
LEESER, ERICH A	
ART UNIT	**PAPER NUMBER**
1624	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,708	BAKKER ET AL.	
	Examiner	Art Unit	
	Erich A. Leeser	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-5,10-15 and 18* is/are allowed.

6)☒ Claim(s) *6-9,16,19 and 20* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3-16-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are currently pending.

Election/Restriction

Acknowledgement is made that Applicant elected with traverse Group III, which is directed to claims 1-15 and 18 drawn to 3-substituted 3,4-dihydrothieno[2,3-d]pyrimidin-4-one derivative compounds and compositions when A = nitrogen, classified in classes 544 and 514, subclasses 250 and 267 respectively. Applicant argues that the invention's point of novelty lies in R3 over the prior art and so the meaning of variable group A is irrelevant. After performing the search, Examiner tends to agree with Applicant and thus withdraws the Restriction Requirement.

Priority

Acknowledgment is made that this application is a 371 of PCT/EP03/14423 and claims foreign priority under 35 U.S.C. 119 to GERMANY 102 59 382.5, filed on December 18, 2002.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the specification does not enable the instant compounds to

treat disorders of the central nervous system, a neuropsychiatric disorder or depression, or enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention:

The instant invention is drawn to various 3-substituted 3,4-dihydrothieno[2,3-d]pyrimidin-4-one derivative compounds, compositions and methods of treating disorders of the central nervous system, a neuropsychiatric disorder or depression to a patient in need thereof.

The state of the prior art:

The state of the prior art involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seeming high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. For example, "the key for the next generation of progress is to unravel the complex

effects of activation/antagonism of the various postsynaptic 5-HT receptors and their significance, *if any*, in mediating the antidepressant response." (Emphasis added). Cryan, J., et al., *5-HT_{1A} and Beyond: The Role of Serotonin and its Receptors in Depression and the Antidepressant Response*, Hum. Psychopharmacol. Clin. Exp. 15, 113-135 (2000). This reference from the time the invention was made shows the speculative nature of the role of 5-HT receptors with the treatment of depression.

The predictability in the art:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the claimed invention is highly unpredictable since one skilled in the art would not necessarily recognize, with regards to therapeutic effects, whether or not the compounds of the invention would be useful for treating disorders of the central nervous system, a neuropsychiatric disorder or depression.

Amount of guidance/working examples:

Beginning on page 38, Applicants provide the correlation between the compounds of their invention and binding activity. There are no examples in the specification; however, showing that the instant compounds can be effectively used for treating disorders of the central nervous system, a neuropsychiatric disorder or depression.

The breadth of the claims:

The breadth of claims is drawn to treating disorders of the central nervous system, a neuropsychiatric disorder or depression.

The quantity of undue experimentation needed:

Since the guidance and teaching provided by the specification is insufficient for treating disorders of the central nervous system, a neuropsychiatric disorder or depression, one of ordinary skill in the art, even with a high level of skill, is unable to use the instant compounds to treat disorders of the central nervous system, a neuropsychiatric disorder or depression as claimed without undue experimentation.

The level of the skill in the art:

The level of skill in the art is high. Due to the unpredictability in the pharmaceutical art; however, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* and *in vivo* screening to determine which compounds exhibit the desired pharmacological activity and which diseases or diseases would benefit from this activity.

Taking all of the above factors into consideration, it is not seen how one of ordinary skill in the art would be able to use the compounds of the present invention for treating disorders of the central nervous system, a neuropsychiatric disorder or depression without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-9 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following apply.

Specifically, claims 6-9 improperly recite the narrowing term "preferably", which makes the scope of these claims unclear. Examiner recommends amending the claims by adding dependent claims to incorporate the further limitations after "preferably" of each of these claims to obviate this rejection.

Similarly, claim 16 uses "such as" to further limit the scope of the claim. Examiner recommends amending the claims by adding a dependent claim to incorporate the claim limitation, "thionyl chloride" to obviate this rejection.

Claim Objections

Claim 17 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The intended use for the claim does not give patentable weight to the claim. Does Applicant intend a non-therapeutic use for some of the compounds?

Allowable Subject Matter

Claims 1-5, 10-15 and 18 are patentable over Steiner et al., United States Patent No. 6,159,981. The reference teaches 3-substituted pyrido[3',4':4,5]thieno[2,3-D]pyrimidine derivative compounds instead of the 3-substituted 3,4-dihydrothieno[2,3-d]pyrimidin-4-one derivative compounds of the instant application. The difference between the compounds of the reference and the compounds of the instant application is R^2 of the reference must be six-

membered rings whereas R3 of the present claims is limited to a five-membered ring. Therefore, the claims are free of prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EL

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